In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-489V

(not to be published)

* *	Chief Special Master Corcoran
KIM BOLDRINI-SENN, *as best friend of O.S.S.*, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Filed: February 21, 2020 Expressive developmental delay; Pneumococcal vaccine; Reasonable basis; Table encephalopathy

Kim Boldrini-Senn, Lake Carmel, NY, *pro se* petitioner.

Voris E. Johnson, Jr., U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE[1]

On April 2, 2019, Kim Boldrini-Senn filed a petition on behalf of OSS, a minor, seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petitioner alleged that the second dose of the pneumococcal conjugate vaccine that OSS received on April 1, 2016, caused him to suffer from lack of muscle control resulting in delayed speech. Petitioner (who was initially represented in this matter by counsel) filed with the Petition some of OSS's medical and school records to support the claim (although they would prove to be the

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

primary medical records filed in this matter).

After assignment to me, I directed the parties to file a joint statement of completion on or before July 1, 2019. (ECF No. 4). However, a preliminary review of the Petition and associated medical records prior to that date suggested to me that the case was not likely to prevail. Although Petitioner had not explicitly characterized OSS's injury as a vaccine-caused autism spectrum disorder ("ASD")), the claim appeared to be substantively similar to numerous claims alleging ASD injuries but rejected in many well-reasoned and carefully-considered Vaccine Program decisions over the past thirteen years, beginning with the Omnibus Autism Proceeding (the "OAP").[3] There was also no record evidence that OSS had experienced the kind of encephalopathic reaction to vaccination that in rare circumstances has been associated with developmental issues. Rather, he displayed the kind of developmental limitations (manifesting weeks or months post-vaccination) that numerous past petitioners had failed to show were vaccine-caused.

Therefore, on June 5, 2019, I held a status conference with the parties to share with Petitioner my reasoned concerns about the weaknesses of her claim—concerns which compelled

[3] Several years ago, more than 5,400 cases were initially filed under short form petition in the OAP, where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately, a total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010. Since that time, *no* non-Table claims alleging autism or behavioral/motor/communication developmental delays have found success under any other theories. Only in rare circumstances (i.e., two cases) have Table claims establishing that a child suffered an encephalopathy that had downstream impact on the child's development (attributable to severe brain injury) have succeeded, but this claim does not allege a Table injury.

me to express the view, early in the case's life, that the claim likely lacked reasonable basis to go forward. (ECF No. 7). Petitioner's counsel conceded that the claim had glaring deficiencies unless it could be better supported by record evidence, and indicated that in response to my comments he would take action in that regard by the July deadline previously set for the Joint Statement of Completion. *Id.* at 3.

On July 1, 2019, Petitioner filed a Motion to Amend Schedule, seeking to extend the deadline for the Joint Statement of Completion to August 16, 2019. (ECF No. 8). I granted the motion and instructed Petitioner to inform me by that date on what basis she intended to proceed with her claim. Then, on August 16, 2019, Petitioner filed *another* motion to amend the schedule—without filing any other new medical records or support for her claim. (ECF No. 9). I denied the motion, and instead directed Petitioner to show cause on or before September 30, 2019, why the case should not be dismissed.

On September 27, 2019, three days before the deadline to show cause, Petitioner's counsel filed a motion to withdraw as counsel of record. (ECF No. 10). I then held another status conference, at which time Ms. Boldrini-Senn indicated that she wanted to continue pursuing her claim *pro se*. (ECF No. 12). I once again expressed my doubts about the validity of her claim as it stood, and informed her that she would need to further support it with record evidence (as I had been requesting her to do since June). Petitioner agreed, and indicated that she would like to have the matter resolved via a ruling on the record, filing her motion on December 6, 2019 (ECF No. 16) ("Mot."). Respondent opposed the motion on December 30, 2019 (ECF No. 22) ("Opp.").

Now, having had the opportunity to review the parties' respective briefs, I deny Petitioner's motion and dismiss her claim. As discussed in more detail below, Petitioner is unable to meet her burden of proof to show entitlement. She has not persuasively or sufficiently addressed the reasoned concerns I set forth at the case's outset about its deficiencies.

I. Brief Factual Summary

OSS was born on March 21, 2015, and had a normal birth with no complications. Ex. 1 at 11, 16–19. In the ensuing year up to the time of the vaccination in question, he had several normal well-child visits, at which time he was administered a number of vaccines without complication. Ex. 2 at 3–4, 6–7, 9, 13, 19, 22–23, 26, 28. Notably, he also received the pneumococcal vaccine in December 2015, with no recorded reaction or adverse symptoms. *Id.* at 4. These records from before the relevant vaccine administration reveal no developmental concerns.

OSS received another dose of the pneumococcal vaccine on April 1, 2016, at the time of his one-year pediatric visit. Ex. 2 at 3, 29. Ms. Boldrini-Senn now expressed some nascent concerns about OSS's demeanor and behavior, noting that he seemed to frequently bump his head,

and that his eyes often seemed to be crossed or lazy. *Id.* at 31–32. OSS did not at this time, however, display after examination any developmental issues to treaters. *Id.* at 30, 33–34. Within a week of this visit, OSS was brought to a pediatrician due to a fever has was running, beginning the day after vaccination. *Id.* at 35. But examination revealed no other concerning issues (and no mention was made of any nascent communication changes or other alarming observations), and treaters suggested (especially given his other complained symptoms of runny nose and loose stools) that OSS likely was experiencing a virus. *Id.* The treating pediatrician advised Ms. Boldrini-Senn to contact his office again if symptoms persisted, but there is no record evidence filed in this case that this occurred.

There is a subsequent six-month gap in the filed records. Then, OSS returned to his pediatrician for an 18-month visit on October 11, 2016. Ms. Boldrini-Senn now expressed more direct concerns about his communication skills, and also noted that she intended to seek early intervention. Ex. 2 at 37. She also conveyed her view that OSS might have some form of allergy to the pneumococcal vaccine, although the record does not expand on the basis for this concern. *Id.* Despite the above, treaters again assessed OSS as developmentally normal. *Id.* at 36–37.

A week later, Ms. Boldrini-Senn took OSS to the Early Childhood Team for Portland, Oregon Public Schools. Ex. 3 at 2. The records from this encounter state that Petitioner had observed problems with OSS's expressive communication—and that this was speculated to be linked to the pneumococcal vaccine he received in April 2016. *Id.* at 7. Indeed, this communication delay was estimated to have begun almost immediately after receipt of the vaccination. *Id.* After evaluation, it was proposed that OSS only showed significant delay in communication, with motor and other skills normal, and a future meeting was set for formulating a treatment plan. *Id.* at 10–11.

The only other records filed in this case are from mid-2017 on. They reveal some efforts to test OSS's hearing. *See, e.g.*, Mot. at 355–57.[4] In addition, it appears OSS received an electroencephalogram[5] which produced no evidence of seizure activity. *Id.* at 357. Nothing else was filed in this case records-wise (a) revealing treater views regarding the role vaccination allegedly played in OSS's communications delay, or (b) substantiating that the pneumococcal vaccine caused any kind of reaction or subsequent symptoms.

[4] A few additional records (the first filed in the matter since its initiation) were directly appended to Petitioner's motion for ruling on record (along with a number of items of literature or other pieces of scientific evidence referenced in the motion) rather than filed as separate exhibits.

[5] An electroencephalogram ("EEG") is an "electrodiagnostic test [] performed to identify and evaluate patients with seizures. Pathologic conditions involving the brain cortex (such as tumors, infarction) can also be detected. The EEG is also a confirmatory test for determination of brain death." K. Pagana et al., *Mosby's Manual of Diagnostic and Laboratory Tests* 490 (6th ed. 2018).

II. Parties' Respective Arguments

Ms. Boldrini-Senn's brief in support of her motion for a ruling on the record makes a number of related arguments in favor of her claim. First, she asserts that (despite a lack of corroborative record evidence) OSS did in fact experience a dramatic reaction to the pneumococcal vaccine, manifesting a fever and respiratory/gastrointestinal symptoms not long thereafter, followed by neurologic issues (falling down, appearing unfocused) and babbling speech that later progressed to a loss of expressive skills. Mot. at 2. She specifically claims that he experienced "seizure activity" which was a symptom of the vaccine-induced brain damage he experienced. *Id.* She attributes OSS's reaction and injury to a "delayed-type hypersensitivity" reaction to the vaccine, which she characterizes as overstimulation of the immune system resulting in tissue damage. *Id.* at 2–3. As a result, the vaccine caused an "override" of OSS's immune system development, leading to chronic illness. *Id.* at 5–6.

Second, she proposes that OSS's alleged reaction could be attributable to what has been called the "ASIA syndrome" (autoimmune inflammatory syndrome induced by adjuvants). Mot. at 3. The pneumococcal vaccine contains an aluminum-based adjuvant - a known neurotoxin, Petitioner maintains, that can also induce an iron deficiency. *Id.* at 3, 4. Petitioner otherwise argues that there are many known side-effects of the pneumococcal vaccine, pointing to various items of evidence like the vaccine's package insert or official government publications. Mot. at 3. She also maintains that (in addition to the role the adjuvant allegedly plays in causing harm) other components of the vaccine can induce an autoimmune reaction, especially if multiple doses of the vaccine are given in temporal proximity (as here, since OSS received the pneumococcal vaccine in December 2015 and then again in April 2016). *Id.* at 5.

Respondent opposes Petitioner's motion and cross-moves for the claim's dismissal. Opp. at 1. He argues that the record in fact does not support Petitioner's allegations, noting that her contentions about OSS's post-vaccination seizure reaction find no record corroboration. *Id.* at 10–11. At best, the record suggests OSS experienced some kind of viral infection around the time of vaccination, but it resolved and was not accompanied by more alarming symptoms requiring medical intervention. Only six months from the date of vaccination did Ms. Boldrini-Senn expressed concerns about OSS's communication skills (although she not long thereafter claimed these developmental delays manifested closer in time to the vaccination). *Id.* at 11. Respondent next notes that Petitioner has offered no expert support for her theory (beyond her own statements arising from her purported medical qualifications to opine), but that the facts of this case make it "inconceivable" that even a qualified expert could offer a credible causation opinion. *Id.* at 12.

Regarding some of Petitioner's specific causal arguments, Respondent notes that the contention that the aluminum adjuvant in the pneumococcal vaccine can induce autoimmunity has been rejected in prior well-reasoned decisions. Opp. at 12 (citations omitted). Similarly, Respondent observes that Petitioner's literature filed in support of her claim is the same evidence that was thoroughly reviewed, and rejected, in the OAP cases. *Id.* at 13. Thus, it deserves little weight despite Petitioner's assertion that she does not allege autism as an injury.

ANALYSIS

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of her vaccinations (in which case establishing causation-in-fact is not required), or (2) that he suffered an injury that was actually caused by a vaccine. *See* Sections 13(a)(1)(A) and 11(c)(1). Petitioners seeking to establish entitlement via a causation-in-fact must meet the three-prong test for such a claim set forth by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005).[6] At best, Petitioner's claim could be viewed as proposing that OSS experienced a post-vaccination brain injury sufficient to cause expressive developmental delay, but that claim would be untenable whether it was framed as a Table or non-Table claim.

First, the evidence filed in this matter does not establish the Table requirements for encephalopathy (i.e., brain injury). I have discussed in prior cases the evidentiary burdens a petitioner must satisfy to establish a child experienced a post-vaccination encephalopathy. *See, e.g.*, *Thompson v. Sec'y of Health & Human Servs.*, No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017) (dismissing Table claim that post-vaccination encephalopathy occurred and resulted in ASD). Here, it is self-evident from the present record that these strict requirements are not met. The contemporaneous medical record does not support the conclusion that OSS experienced an acute (meaning sufficient to require hospitalization) or subsequent chronic encephalopathy after his April 2016 pneumococcal vaccination. At most, he had a transient reaction (fever), that never required additional follow-up treatment (as underscored by the absence of filed medical records for the period between mid-April and late September 2016—the exact time period in which there should be ample record evidence of encephalopathy). I also give limited weight to after-the-fact statements about the purportedly severe developmental delay observed in OSS post-vaccination, as such statements are not corroborated by contemporaneous medical

[6] I do not include a detailed review of the legal standards applicable in the Program herein, because I do not find that the allegations in this case rise above the reasonable basis standard—that is, there was insufficient reasonable basis for this claim to be brought in the first place, a conclusion supported merely by the procedural history (during which time prior counsel withdrew from the case after proving unable to offer evidence he acknowledged was necessary for the claim to become tenable).

record evidence. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947)).

Second, the record and other evidence filed herein does not support a non-Table, causation-in-fact claim that OSS experienced any kind of injurious reaction to the pneumococcal vaccine sufficient to produce expressive communication delay (even assuming this injury is distinguishable from autism—an injury that can no longer be credibly advanced in the Program, at least given the current state of science on the lack of relationship between autism and vaccines generally). As noted, there is little in the record that would corroborate allegations of a post-vaccination brain injury after April 1, 2016. At most, OSS experienced a post-vaccination, transient reaction (evidenced by fever) that resulted in some medical pediatric treatment but which did not progress to his hospitalization or other pointed treater intervention. The first concern expressed by Petitioner in the medical records that OSS might have any kind of developmental delay comes from October 2016—six months later, with no intervening records to suggest this occurred immediately post-vaccination, despite Petitioner's contentions, and with one medical record close-in-time to OSS's alleged developmental onset saying nothing about it. There is also no treater support for Petitioner's contentions. All that remains is the fact that Ms. Boldrini-Senn's observations of OSS's developmental delays led her to seek intervention six months *after* the April vaccination—too attenuated a temporal association for a successful Program claim. *McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997).

In addition, certain of the various causal theories that Petitioner's motion proposes are facially inadequate (and would be so even if Petitioner had obtained a credentialed expert to offer them formally). As Respondent's opposition notes, the concept that the aluminum adjuvant in vaccine can cause neurologic injury has been persuasively rejected. Opp. at 12. I myself have refused to permit petitioners to offer the ASIA theory in several cases, finding (as other special masters have noted) that it is patently unreliable as a scientific concept. *See, e.g.*, *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760, at *7 n.11 (Fed. Cl. Spec. Mstr. Mar. 23, 2018). And I am aware of no cases in which a claimant successfully established that the other components of the pneumococcal vaccine could induce an autoimmune reaction over the several-month timeframe at issue in this case resulting in developmental delay, especially in the absence of evidence of an immediate post-vaccination reaction that did not resolve quickly (as here). The same is true for the assertion that the vaccine somehow impacted the maturation of his immune process, whether triggered by a hypersensitivity reaction or otherwise.

Finally, Petitioner has not successfully distinguished this case from the many autism claims that have been litigated unsuccessfully in the Program. I noted in *Thompson* that non-Table claims alleging a vaccine-caused developmental problem (whether or not the petitioners explicitly

embrace autism as the claimed injury[7]) decided since the conclusion of the OAP have uniformly failed. *Thompson*, 2017 WL 2926614, at *13 (citing *Wolf v. Sec'y of Health & Human Servs.*, No. 14-342V, 2016 WL 651858, at *15 (Fed. Cl. Spec. Mstr. Sept. 15, 2016)). The same is true for non-Table claims attempting to characterize developmental symptoms as the *secondary* result of a vaccine-induced encephalopathy. *Id.* at *13 (citing *Cunningham v. Sec'y of Health & Human Servs*., No. 13–483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Aug. 1, 2016) *mot. for review denied*, 2017 WL 1174448, at *5 (Fed. Cl. March 22, 2017) (disregarding "petitioner's attempt to differentiate this case from other autism cases by creating this second step"—that post-vaccination developmental regressions can be attributed to a vaccine-induced encephalopathy even if there is no evidence of an encephalopathic reaction)). These cases underscore why proceeding with this case would be unreasonable given the present record—and why I informed Petitioner of my view that the claim was not tenable not long after its filing.[8]

CONCLUSION

I have no doubt that Petitioner has brought this claim in the good-faith belief that her son was harmed by a vaccine, and that she is motivated by the desire to provide him the best care possible. However, under the Vaccine Act, a petitioner may not receive a Program award based solely on her claims alone. Rather, the petition must be supported by either medical records or by

[7] Petitioners in the post-OAP world have frequently attempted to mask what otherwise look like autism claims as claims a vaccine caused some other immediate injury that had downstream impact on a child's development. Such efforts have been observed by the Court of Federal Claims to be what they are, however. *See, e.g., Cunningham v. Sec'y of Health & Human Servs.*, No. 13–483V, 2017 WL 1174448, at *5 (Fed. Cl. Jan. 25, 2017) ("the Special Master rightfully classified this case as an autism case, and, in treating it as such, did not raise the petitioner's burden of proof.").

[8] I note that Petitioner also has made a request (within a pleading that was not the correct vehicle for the relief sought) that I recuse myself from this case, claiming that my comments to her about the claim's lack of reasonable basis suggested bias on my part that impacted my impartiality in presiding over this matter. Notice of Intent to Remain in the Program, filed on Feb. 2, 2020 (ECF No. 24) ("Recusal Request"). Of course, this does not constitute a proper motion, and therefore need not be addressed at all. However, I would have denied such a motion had it been properly interposed. Recusal of federal judges (including special masters) is governed by 28 U.S.C. § 455. The Supreme Court has clarified that "the alleged bias and prejudice to be disqualifying *must stem from an extrajudicial source* and result in an opinion on the merits on some basis *other than what the judge learned from his participation in the case*." *United States v. Grinnell Corp*., 384 U.S. 563, 583 (1966) (emphasis added); *see also Schultz v. Sec'y of Health & Human Servs.*, No. 16-539V, 2019 WL 6359139, at *3–6 (Fed. Cl. Spec. Mstr. Oct. 9, 2019) (discussing standards for recusal).

Here, Petitioner complains of comments made in course of status conferences, orders, and proceedings relevant solely to this claim. *See* Recusal Request at 2. Those comments, moreover, reflect the kind of inquisitorial function special masters are expected to perform; special masters frequently explain to claimants what they see as deficiencies in a particular claim, and will also inform petitioners that they believe a claim may lack a reasonable basis entirely, in the hopes that the claimant will take such comments seriously, no matter how disappointing they may be. This is especially important when a claim alleges the kind of injury that has almost never been successful in the Program. For such reasons, Petitioner would not have been able to establish grounds for recusal under the circumstances.

the opinion of a competent physician. Section 13(a)(1). In this case, there is insufficient evidence in the record for Petitioner to meet her burden of proof, especially given the nature of injury alleged. In fact, the claim lacked reasonable basis to be brought at all, given the ample Program precedent relevant to a claim that a vaccine induced a developmental delay (regardless of whether it is openly characterized as an ASD or not). Petitioner's claim therefore cannot succeed and must be dismissed. Section 11(c)(1)(A).

Thus, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.[9]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite judgment by filing a joint notice renouncing their right to seek review.